JUL 2 9 2004

510(k) SUMMARY

A. Submitter Information:

Submitter:	MEDCOMP® 1499 Delp Drive Harleysville, PA 19438 (215) 256-4201 Telephone (215) 256-9191Fax
Contact:	Jean Callow Regulatory Specialist
Date Prepared:	March 24, 2004

B. Trade Name:

Trade Name:	Medcomp Excell™ Split-Tip Catheter
Common Name:	Hemodialysis Catheter, Implanted
Classification:	78 MSD
C.F.R. Section:	876.5540

C. Predicate Device:

K010306 Excell™ Split-Tip Catheter
K012562 14.5F Double Lumen Hemodialysis Catheter
K030502 14.5F x 55cm Hemo-Flow™ Double Lumen Catheter

D. Device Description:

The Medcomp Excell™ Split-Tip Catheter is a 15F polyurethane, double lumen catheter used to remove and return blood through two, segregated lumen passages. Both lumens are "D" shaped, open at the distal tip, with two side holes. The distal venous lumen is tapered and extends beyond the arterial lumen to reduce recirculation. The fixed polyester cuff allows for tissue ingrowth for long-term placement.

The arterial and venous lumens now are designed to be split, or peeled apart, prior to insertion to provide two free-floating lumens within the vessel. The lumens are connected to the extensions via a soft pliable hub with suture wing. The arterial and venous extensions are identified by red and blue luer connectors and clamps. Priming volume information is printed on the I.D. rings for ease in identification.

E. Intended Use:

The Medcomp Excell™ Split-Tip Catheter is indicated for use in attaining long-term vascular access for hemodialysis and apheresis. It may be inserted percutaneously and is primarily placed in the internal jugular vein. Alternate insertion sites include the subclavian vein as required. Catheters greater than 40cm are intended for femoral vein insertion.

F. Comparison to Predicate Device:

The proposed device is a product-line extension to the legally marketed device, and is similar in design and materials.

The modifications include:

- Double "D" shaped lumens
- 55cm length
- Femoral insertion instructions for use
- Splittable lumens

G. Performance Data:

In vitro performance data for the proposed device including recirculation, gravity flow, flow vs. pressure performance, and lumen peel testing demonstrate that this device is substantially equivalent to legally marketed devices intended for hemodialysis and apheresis treatments.

Clinical studies were not deemed necessary since in vitro testing was sufficient to demonstrate safety and effectiveness by way of comparison to legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 29 2004

Ms. Jean Callow
Regulatory Specialist
MedCOMP®
1499 Delp Drive
HARLEYSVILLE PA 19438

Re: K040992
Trade/Device Name: Medcomp® Excell™/Dynamic Flow Split-Tip Catheter
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: 78 MSD
Dated: July 14, 2004
Received: July 19, 2004

Dear Ms. Callow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation, please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K040992

Device Name: MEDCOMP EXCELL™ SPLIT-TIP CATHETER

Indications for use:

THE MEDCOMP EXCELL™ SPLIT-TIP CATHETER IS INDICATED FOR USE IN ATTAINING LONG TERM VASCULAR ACCESS FOR HEMODIALYSIS AND APHERESIS.

IT MAY BE INSERTED PERCUTANEOUSLY AND IS PRIMARILY PLACED IN THE INTERNAL JUGULAR VEIN.

ALTERNATE INSERTION SITES INCLUDE THE SUBCLAVIAN VEIN AS REQUIRED.

CATHETERS GREATER THAN 40CM ARE INTENDED FOR FEMORAL VEIN INSERTION.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter _____
(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040992

(Optional Format 1-2-96)